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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,774	12/14/2005	Fabien Schweighoffer	BJS-3665-167	5165

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EXAMINER	
JAVANMARD, SAHAR	

ART UNIT	PAPER NUMBER
1627	

MAIL DATE	DELIVERY MODE
03/30/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,774	SCHWEIGHOFFER ET AL.	
	Examiner	Art Unit	
	SAHAR JAVANMARD	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on January 7, 2010. Claim(s) 12-14 are pending and are examined herein.

Response to Arguments

Applicant's arguments with respect to the 103(a) rejection of claims 12-14 as being unpatentable over Ikhlef et al. (US Pub. No. 2003/0064374 A1) in view of Schumacher et al. (US Patent No. 7,153,871 B1) has been fully considered but is not persuasive.

Applicant argues that the claims require monitoring the treated patient for improvement in perceptive cognition after administering etazolate. Applicant further contends that Ikhlef teaches away from monitoring a treated patient for improvement in perceptive cognition after administering etazolate as Ikhlef teaches that an advantage of the Ikhlef method is not monitoring the symptoms accompanying the treated neurodegenerative disease.

In response to this argument, Examiner respectfully notes that it would be obvious to one of ordinary skill in the art to know that if a particular treatment regimen, in this case, etazolate, is effective in treating Alzheimer's disease, then it would be obvious that one would observe this effectiveness by monitoring the patient. Furthermore, Schumacher is employed to demonstrate the types of patient monitoring

that is performed upon administration a PDE4 inhibitor. Examiner is aware that the compounds taught by Schumacher are structurally different from that of etazolate. As set forth on record, the Schumacher reference was employed to demonstrate the varying monitoring techniques available upon administration of a PDE4 inhibitor.

Applicant further brings forth arguments regarding an application that was examined by Examiner Gibbs and his interpretation of the Ikhlef reference. Respectfully, Examiner will not address arguments with regard to the office actions of another examiner on any given case.

Based on reasons of record, the rejection of the previous office action are hereby maintained and have been included in the final Office action below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ikhlef et al. (US Pub. No. 2003/0064374 A1) in view of Schumcher et al. (US Patent No. 7,153,871 B1).

Ikhlef teaches treating neurodegenerative diseases, including ALS and Alzheimer's disease with the use of etazolate, which is a PDE4 inihibtor (page 4, [0056]; claims 9, 12-14, and 17).

Ikhlef teaches that etazolate may be administered by any method known in the art preferably injection, namely the intravenous route (page 4, [0058]).

Ikhlef does not specifically teach treating cognitive deficits or the monitoring thereof.

Schumacher teaches a class of aminoindazole and aminobenzofuran analogs as a method of treatment that involves the inhibition of PDE4 enzymes. The invention includes methods of selective inhibition of PDE4 enzymes in animals, e.g., mammals, especially humans, wherein such inhibition has a therapeutic effect, such as where such inhibition may relieve conditions involving neurological syndromes, such as the loss of memory, especially long-term memory (column 2, lines 29-36).

Schumacher teaches the condition of memory impairment is manifested by impairment of the ability to learn new information and/or the inability to recall previously learned information. Memory impairment is a primary symptom of dementia and can also be a symptom associated with such diseases as Alzheimer's disease, schizophrenia, Parkinson's disease, Huntington's disease, Pick's disease, Creutzfeld-Jakob disease, HIV, cardiovascular disease, and head trauma as well as age-related cognitive decline (column 2, lines 41-49).

Dementias are diseases that include memory loss and additional intellectual impairment separate from memory. The present invention includes methods for treating patients suffering from memory impairment in all forms of dementia. Dementias are classified according to their cause and include: neurodegenerative dementias (e.g., Alzheimer's, Parkinson's disease, Huntington's disease, Pick's disease), vascular (e.g., infarcts, hemorrhage, cardiac disorders), mixed vascular and Alzheimer's, among others column 18, lines 50-55).

Schumacher teaches two methods of monitoring cognitive improvement upon administration of the PDE4 inhibitors, including *in vivo* testing for learning and memory 1)passive avoidance in rate, 2) radial arm maze task (column 26, example 11, methods A and B)

It would have been obvious to one of ordinary skill in the art at the time of the invention to have treated Alzheimer's disease with the administration of etazolate, as taught by Ikhlef and also treated perceptive cognition. The motivation, provided by Schumacher, teaches that PDE4 inhibition is employed as a method of treatment for

neurodegenerative dementias, namely Alzheimer's disease, to improve loss of memory, especially long term memory. Thus, it would have been obvious to one of ordinary skill in the art to have expected, with a reasonable degree of success that a PDE4 inhibitor, namely etazolate, which is effective in treating Alzheimer's disease, can also be employed to improve cognition based on reasons of record. One would expect that because both classes of compounds are PDE4 inhibitors and employed to treat Alzheimer's disease that one of ordinary skill in the art would expect, with a reasonable degree of success, that the former, namely etazolate, would also be an obvious candidate, to at least try, as a method of improving the cognitive aspect of Alzheimer's disease. Additionally, it would have been obvious to have employed the monitoring methods of Schumacher to gauge the effectiveness of the medicament. Thus, based on the reasons of record, the instant claims are deemed unpatentable over the cited art.

Conclusion

Claims 12-14 are not allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/S. J./

Examiner, Art Unit 1627

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627